APR 19 2011

5. 510(k) Summary

J. Y. Laboratory Inc.
982 Trans-Canada, Longueuil, Quebec, Canada J4G 2M1
Tel: 450-674-6886; Fax: 450-674-8282; Website:
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SUMMARY

Submitter's name:	Jieying Laboratory Inc.
Address:	982 Trans-Canada Longueuil, Quebec Canada J4G 2M1
Phone:	+1 450 674 6886
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Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821
Date Summary was revised:	April 15, 2011

Name of the devices:

a. Injection pipette;
b. Holding pipette;
c. Biopsy pipette;
d. Polar body biopsy pipette;
e. Denuding pipette;
f. Partial zona dissection (PZD) pipette;
g. Assisted hatching (AH) pipette.

Trade or proprietary name:	Jieying Laboratory Inc. Micro-Manipulation Pipettes
Common or usual name:	Assisted reproduction microtools or pipettes
Classification name:	Microtools, Assisted Reproduction (Pipettes)

K102480

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

Jieying Laboratory Device	Predicate Device Name	Predicate K Reference	Applicant
Injection pipette	Intracytoplasmic Sperm Injection Micropipets (ICSI)	K990847	Humagen Fertility Diagnostics, Inc.
Holding pipette	Holding Micropipets	K990847	Humagen Fertility Diagnostics, Inc.
Biopsy pipette	Blastomere Biopsy Micropipet	K012811	Humagen Fertility Diagnostics, Inc.
Polar body biopsy pipette	Polar Body Biopsy Micropipet	K012811	Humagen Fertility Diagnostics, Inc.
Denuding pipette	Denuding Micropipettes	K990847	Humagen Fertility Diagnostics, Inc.
Partial zona dissection (PZD) pipette	Partial Zona Dissection (PZD) pipette	K990847	Humagen Fertility Diagnostics, Inc.
Assisted hatching (AH) pipette	Assisted Hatching (AH) Micropipets	K990847	Humagen Fertility Diagnostics, Inc.

Description of the device:

The following Jieying Microtools are made of glass capillary tubing. They range in sizes and have various degrees of beveled angles as necessary for each individual application. They are gamma radiated and tested for endotoxin and mouse embryo. These devices are assisted reproduction microtools/pipettes that are used in the laboratory to denude, micromanipulate, or hold human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

a. Injection pipette;
b. Holding pipette;
c. Biopsy pipette;
d. Polar body biopsy pipette;
e. Denuding pipette;
f. Partial zona dissection (PZD) pipette;
g. Assisted hatching (AH) pipette.

Indications:

The manufactured microtools are to be used for Assisted Reproductive Technology (ART) and Reproductive Medicine (RM), and the specific pipette indication is as follows:

Injection Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories for intracytoplasmic sperm injection (ICSI)

Holding Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories for holding oocyte or embryo during ICSI or biopsy

Biopsy Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of blastomere(s) from embryos, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s)

Polar Body Biopsy Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of polar bodies from oocytes, which may be done in order to perform pre implantation genetic diagnosis on the genetic material in the biopsied cell(s)

Assisted Hatching Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories to create a defect in the zona pellucida chemically using Tyrode's acid solution in order to perform assisted hatching of embryos

Denuding Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories to denuding cumulus cells from oocytes by delivering enzymes to aid separation

Partial Zona Pipette: tool used in IVF/Assisted Reproduction Technology (ART) laboratories to cut zona pellucida to create a defect in the zona pellucida mechanically in order to perform assisted hatching of embryos mechanically

Summary of the technological characteristics of our device compared to the predicate devices:

The Jieying Laboratory Devices have the same technological characteristics (i.e., testing, design, material, shapes and sizes) as the predicate devices.

LAL and MEA testing performed:

LAL (Limulus Amboycte Lysate) testing is performed on each batch of microtools. The level of endotoxin units must be less than 20 EU/device to be considered acceptable.

MEA (Mouse Embryo Assay) is cultured 1-cell zygotes together with the broken tip of the pipette for 96 hours in 37°C, 5% CO2 incubator. The product is considered non-toxic if the percentage of embryos developing to blastocyst stage is greater than 80%.

Sterility And Shelf-Life Evaluations:

Sterility testing was done on samples that were over two years of age. All test samples passed sterility testing. Shelf-Life has been set at two years.

The predicates and the Jieying Laboratory Inc. microtools were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for Use
Design
Materials
Safety Features
Sterility
Manufacturing Technique

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Jieying Laboratory, Inc.
c/o Ms. Grace Holland
Regulatory Specialist
Regulatory Specialist, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

APR 19 2011

Re: K102480
Trade Name: Micro-Manipulation Pipettes (Injection Pipette, Holding Pipette, Biopsy Pipette, Polar Body Biopsy Pipette, Denuding Pipette, Partial Zona Dissection Pipette, Assisted Hatching Pipette)
Regulation Number: 21 CFR §884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: MQH
Dated: April 5, 2011
Received: April 12, 2011

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Injection Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories for intracytoplasmic sperm injection (ICSI).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102480

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4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Holding Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories for holding oocyte or embryo during ICSI or biopsy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Biopsy Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of blastomere(s) from embryos, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K102480

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Polar Body Biopsy Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of polar bodies from oocytes, which may be done in order to perform pre implantation genetic diagnosis on the genetic material in the biopsied cell(s).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K102480

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Denuding Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories to denuding cumulus cells from oocytes by delivering enzymes to aid separation

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K102480

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4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Partial Zona Dissection Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories to cut zona pellucida to create a defect in the zona pellucida mechanically in order to perform assisted hatching of embryos mechanically.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K102480

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102480

Device Name: Assisted Hatching Pipette

Indications for Use:

Tool used in IVF/Assisted Reproduction Technology (ART) laboratories to create a defect in the zona pellucida chemically using Tyrode's acid solution in order to perform assisted hatching of embryos.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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